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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,879	03/22/2001	Takuya Watanabe	2553US0P	9847

23115 7590 07/29/2003

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
INTELLECTUAL PROPERTY DEPARTMENT
475 HALF DAY ROAD
SUITE 500
LINCOLNSHIRE, IL 60069

EXAMINER

BASI, NIRMAL SINGH

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 07/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,879

Applicant(s)

Takuya Watanabe et al

Examiner

Nirmal S. Basu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 22, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1. Notice of References Cited (PTO-892) | 4. Interview Summary (PTO-413, Paper No. 5) |
| 2. Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5. Notice of Informal Patent Application (PTO 152) |

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DETAILED ACTION

1. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted. The invention must be elected from among the following Groups:

Group I, claims 1-9, 15, 17, 20 and 21 drawn to a G protein coupled receptor (GPCR) protein, polynucleotide encoding said GPCR, recombinant vector comprising said polynucleotide, a ligand for said GPCR using said GPCR protein.

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Group II, claims 10-12, drawn to antibody which bind to the GPCR of Group I.

Group III, claims 13-14, drawn to ligand for the GPCR protein of Group I.

Group IV, claim 16, drawn to method for screening a compound which alters binding of a ligand with the GPCR protein of Group I.

5 Group V, claims 18-19, drawn to a compound which alters the binding of a ligand with the GPCR of Group I.

Group VI, claim 22, drawn to method for quantitating a mRNA for the GPCR protein of Group I, which comprises using the polynucleotide encoding the GPCR of Group I.

10 Group VII, claim 23, drawn to method for quantitating the GPCR protein of Group I which comprises using antibody.

Group VIII, claim 24, drawn to method for diagnosing disease associated with the function of the GPCR of Group I which comprises using the qualitative method of Group VI.

Group IX, claim 24, drawn to method for diagnosing disease associated with the function of the GPCR of Group I which comprises using the qualitative method of Group VII.

15 Group X, claim 25, drawn to method for screening a compound which alters an amount of the GPCR protein of Group I using the qualitative method of Group VI.

Group XI, claim 26, drawn to method for screening a compound which alters an amount of the GPCR protein of Group I in a cell membrane using the qualitative method of Group VII.

20 Group I obtainable by using the method for screening according to Group X.

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Group XIII, claim 28, drawn to a compound which alters an amount of the GPCR protein of Group I obtainable by using the method for screening according to Group XI.

The inventions listed as Groups I - XIII do not relate to a single general inventive concept
5 under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical
feature for the following reasons. Group I is drawn to a G protein coupled receptor (GPCR) protein,
polynucleotide encoding said GPCR, recombinant vector comprising said polynucleotide,
transformant transformed with said recombinant, polynucleotide which hybridizes with said GPCR,
method for producing said GPCR, kit comprising said GPCR protein, and method for determining
10 a ligand for said GPCR using said GPCR protein, which is the first appearing product, method of
making and method of using.

The claims of Group I-XIII are drawn to a multitude of nucleic acids, SEQ ID NOs: 3 and
4 encoding the GPCR protein of SEQ ID NOs:1 and 2, respectively, compounds/ligands that bind
said GPCR, agents that alter binding of said compounds/ligands to said GPCR, and methods which
15 use said nucleic acids, or of use of their encoded polypeptides. The claims apply to structurally and
functionally different nucleic acids and their encoded polypeptides. This constitutes recitation of an
implied, mis-joined Markush group that contains multiple, independent and distinct inventions. The
specification, page 83, discloses SEQ ID NO:1 and SEQ ID NO:2 show amino acid sequence of
20 different nucleic acids polypeptides antibodies compounds ligands and methods of use are

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independent and distinct because GPCRs, although having seven transmembrane domains bind different ligands and have different functional properties. The GPCR of SEQ ID NO:1 and 2 have not been shown to bind the same ligand or have the same functional properties. There is no description of definitive structural or functional features of the claimed Markush group. The

5 Markush group contains no conserved regions which is critical to the structure and function of the genus claimed. The common function of the claimed genus of polynucleotides/polypeptides, which is based upon a common property or critical technical feature of the genus claimed is not disclosed.

Accordingly, these claims are subject to restriction under U.S.C. § 121. Upon election of Groups I-XIII, Applicants is additionally required to elect a single nucleic acid (SEQ ID NO: 3 or 4) and its

10 corresponding encoded protein (SEQ ID NO:1 or 2). This requirement is not to be constructed as a requirement for election of species, since each of the compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

The methods of each group are materially different process steps; the process steps are the

15 technical features which distinguish each method from the others. The products of each group are materially different, structurally and functionally which distinguish each product from the others. Because the process steps and products do not share the same or a corresponding special technical feature, unity of invention is lacking. The claims are not so linked by a special technical feature

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Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently
5 named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Advisory Information

10 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

15 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

20 Nirmal S. Basi
Art Unit 1646
July 24, 2003

ADVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600



RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

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COMMENTS: _____

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